UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,657	12/22/2004	Cinderella Christina Gerhardt	F7649(V)	9203

201 7590 04/21/2009

UNILEVER PATENT GROUP
800 SYLVAN AVENUE
AG West S. Wing
ENGLEWOOD CLIFFS, NJ 07632-3100

EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
04/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,657	GERHARDT ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5 and 7-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5 and 7-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :20090120; 20080915; 20080513; 20080421.

1. Claims 1, 3-5, and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, lines 6-7, recites two conflicting molecular weight fractions, i.e. 7 to 12 % in the range 5000 to 1000 Dalton, and 15 to 25% in the range 2000 to 5000 Dalton (the latter molecular weight range is entirely encompassed by the former range). It is believed that at claim 1, line 7, "1000" should instead be "10,000".

2. Claim 9 is objected to because of the following informalities: At claim 9, lines 3 and 5, "soluble powdered product" is repeated. Appropriate correction is required.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, and 7-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-10, 12, 13, and 15-17 of copending Application No. 10/539,434. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '434 application

anticipate instant claims 1, 3, 5, and 7-9. Because the same active agent is being administered to the same subject according to the same method steps, inherently obesity and/or being overweight will be prevented in the claimed method of the '434 application to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the claimed method of the '434 application and the instant claimed method to shift the burden to Applicants to provide evidence that their claimed method is unobviously different than the claimed method of the '434 application. Further, the '434 application claims its method as part of a dietary plan or a weight management program (see claim 7 of the '434 application). With respect to instant claim 4, while the '434 application claims the use of a mixture of hydrolysates of β-lactoglobulin and α-lactalbumin, the '434 application does not claim a weight ratio for these two components. It would have been obvious to one of ordinary skill in the art to determine all operable and optimal component ratios for the hydrolysates of β-lactoglobulin and α-lactalbumin administered in the claimed method of the '434 application, because component ratio is an art-recognized result-effective variable which is routinely determined and optimized in the food and drug arts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Instant claims 1, 3-5, and 7-9 are deemed to be entitled under 35 U.S.C. 119(a)-(d) to the benefit of the filing date of the foreign priority application EPO 02254622.0 because the foreign priority application, under the test of 35 U.S.C. 112, first paragraph, discloses the instant claimed invention.

5. Applicant's arguments filed January 20, 2009 have been fully considered but they are not persuasive.

With respect to the provisional obviousness-type double patenting rejection set forth in section 3 above, the procedures of MPEP 804(I)(B) are applicable.

The anticipation rejection based upon Davis et al (U.S. Patent No. 6,630,320) is withdrawn in view of the amendment to claim 1 reciting the molecular weight profile. Note that the recited molecular weight profile, which has relatively large fractions of high molecular weight and low molecular weight peptides and relatively small fractions of medium molecular weight peptides, is not a typical molecular weight profile for a protein hydrolyzate. Davis et al do not teach or suggest such a molecular weight profile. Further, the prior art of record does not teach or suggest that there is any connection between the molecular weight profile of a protein or whey hydrolyzate and the cellular release of glucagon-like peptides and cholecystokinins, or between the molecular weight profile of a protein or whey hydrolyzate and the treatment or prevention of obesity, and accordingly there is no motivation or suggestion in the art to optimize the molecular weight profile of a whey protein hydrolyzate in order to achieve the claimed effects. For analogous reasons, the prior art rejections based upon the Aoyama et al article (Biosci. Biotechnol. Biochem., Vol. 64, pages 2594-2600) and upon the Demling et al article (Ann. Nutr. Metab., Vol. 44, pages 21-29) as the primary references are withdrawn.

6. The WO Patent Application 01/85984 has been carefully considered but is not deemed to anticipate or render obvious the claimed invention. The WO Patent Application '984 teaches a whey protein hydrolysate at page 10, line 18 - page 11, line 27, which is formed from BiPro whey protein isolate and which has a molecular weight profile consistent with that recited in instant claim 1. However, the WO Patent Application '984 at page 20, line 4 - page 21, line 13, also teaches a molecular weight profile for what appears to be the same whey protein hydrolysate

which does not meet the requirements of the molecular weight profile recited in instant claim 1. (The reference appears to use the designation "601K" and "601" interchangeably to refer to the same whey protein hydrolysate.) The WO Patent Application '984 does not teach administration of the 601/601k whey protein hydrolysate to a human subject, as is required by the instant claims. In view of the uncertainty of the chemical composition of the 601/601K whey protein hydrolysate, the lack of any teaching that it is administered to a human subject, and the lack of disclosure in the WO Patent Application '984 as to the treatment or prevention of obesity or being overweight, the reference is not applied against the instant claims.

As taught at page 25, lines 7-12, of Applicants' specification, the molecular weight profile which has been inserted into claim 1 is that of a commercially available product, Biozate 1. However, the examiner has been unable to locate any prior art (see section 4 above) teaching that Biozate 1 has been administered to a human subject. The Pins et al abstract (Cardiovascular Drugs and Therapy, Vol. 16, Suppl. 1, page 68) teaches administration of a hydrolyzed whey protein to humans, but does not otherwise identify or characterize the hydrolyzed whey protein. The Nutraceuticals World article (Nov, 2002) indicates that the hydrolyzed whey protein used in the Pins et al abstract was Biozate 1; however, the Nutraceuticals World article is not prior art to Applicants' invention. To the extent that Biozate 1 might have been named as the hydrolyzed whey protein at the conference at which the Pins et al abstract was printed, the conference was in Montreal, Quebec, Canada, and any such disclosure would not satisfy the requirement of 35 U.S.C. 102(a) for public knowledge or use "in this country".

The Kelly et al article (The World of Food Ingredients, October/November 2002, pages 24-26, 28, 30, and 32) is cited as art of interest, teaching "Biozate" and its testing in human clinical trials. However, the Kelly et al article does not teach which Biozate is being tested (Applicants' specification at page 15, line 6, indicates that there are at least three different products named "Biozate") and does not contain any disclosure relating Biozate to obesity, being overweight, or induction of cellular release or glucagon-like-peptides or cholecystokinins.

7. Aside from the provisional issue of obviousness-type double patenting, claims 1, 3-5, and 7-9 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, and the claim objection set forth in this Office action.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
April 21, 2009